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REMARKS

Claims 22-55 are in this application. Claims 38-54 have been newly added and correspond to original claims 1, 3, 4, 6-11 and 13-21. Claims 22-37 have been withdrawn subject to rejoinder upon the allowance of the elected product claims (see MPEP 21.04). Claims 1-21 are cancelled.

Support for the amendment to paragraph [0033] is based on the knowledge of those in the art. Attached are a number of references that describe that Adapalene, Tretinoin, Isotretinoin, Motretinide, Retinoic acid and Tazarotene are retinoids and that Benzoyl peroxide, Dichloroacetic acid, Glutaraldehyde, Resorcinol, Salicylic acid, Algestone acetophenide, Azelaic acid, Cioterone, Cyproterone and Tioxolone are used for the treatment of acne. This amendment is not new matter.

According to the Official Action, claims 1-21 are rejected under 35 USC 112, first paragraph as failing to comply with the written description requirement. This is respectfully traversed.

This rejection is not understood by the applicants. There is a description of retinoids, steroids and antifungals in the specification on pages 10-12. The application also includes examples of compositions of this invention.

Therefore, it is respectfully requested that this rejection be withdrawn.

According to the Official Action, claims 1-21 are rejected under 35 USC 112, first paragraph as failing to comply with the written description requirement and as not being enabled because of the inclusion of "prodrugs" in claim 1. This is respectfully traversed.

However, in view of the deletion of the term "prodrugs" from the independent composition claim, it is respectfully requested that these rejections be withdrawn because they are moot.

According to the Official Action, claims 1-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of US patent 6,514,986 and claims 1-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of US patent 6,608,078.

Claims 1-12 of US patent 6,514,986 claim polymorphs or are related to polymorphs of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]benzoquinolizine-2-carboxylic acid, arginine salt. Claims 1-6 of US patent 6,608,078 relate to 8-(substituted piperidino)-benzo[i,j]quinolizines. As the claims in this application are related to a pharmaceutical composition comprising a combination of benzoquinolizine-2-carboxylic acid with one or more other pharmaceutically active ingredients such as retinoids, steroidal and non-steroidal anti-inflammatory compounds and anti-fungal drugs, it is respectfully requested that the obviousness type double patenting rejections be withdrawn as the claimed invention is not obvious over the claims of either patent. None of the claims of either patent disclose or suggest the pharmaceutical combination claimed in this application. Furthermore, according to claim 1 of the '078 patent, column 48, lines 26-27, when R1 is hydrogen, R2 is not hydrogen and column 48, line 39, R1, R2 and R3 are not equal to hydrogen at the same time. As currently amended, the claims require that R (corresponding to R3 in claim 1 of the '078 patent), R1 and R2 are all hydrogen.

Claims 1-6 and 20-21 are not anticipated by the claims of the '986 and '078 patents.

Anticipation requires that the each and every element of the claim be disclosed in the cited reference. As explained above, the independent claim 38 of this application relates to a pharmaceutical composition comprising a combination of benzoquinolizine-2-carboxylic acid with

one or more other pharmaceutically active ingredients such as retinoids, steroidal and non-steroidal anti-inflammatory compounds and anti-fungal drugs. The other claims all depend, directly or indirectly from claim 38. The combinations of claim 38 and the dependent claims are not disclosed in either of the cited patents and therefore, as each and every element of the claim is not disclosed, the anticipation rejections must be withdrawn.

According to the Official Action, claims 1-9, 12 and 20-21 are obvious over the combination of US patents 6,514,986 and 6,608,078. This is respectfully traversed.

The standard test used to establish *prima facie* obviousness is the test set out by the Supreme Court in *Graham v. John Deere* (383 US 1, 148 USPQ 459 (1966)). To determine whether a claim is *prima facie* obvious:

- 1) the scope and content of the prior art are to be determined;
- 2) the differences between the prior art and the claims at issue are to be ascertained;
and
- 3) the level of ordinary skill in the pertinent art resolved.

In addition, according to MPEP 2141, citing *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n. 5 (Fed. Cir. 1986), when applying 35 USC 103, the following tenets of patent law must be adhered to:

- 1) the claimed invention must be considered as a whole;

- 2) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; and
- 3) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention.

The reason, suggestion or motivation to combine references may be found explicitly or implicitly. While the references need not expressly teach that the disclosure contained therein should be combined with another, the showing of combinability must be clear and particular. *Ruiz v. A.B. Chance Co.*, 57 USPQ2d 1161 (Fed. Cir. 2000).

As neither reference either alone or in combination discloses or suggests a composition of pharmaceutical composition comprising a combination of benzoquinolizine-2-carboxylic acid with one or more other pharmaceutically active ingredients such as retinoids, steroidal and non-steroidal anti-inflammatory compounds and anti-fungal drugs, there is no reason, suggestion or motivation that leads to the invention of claims 38-55. It is therefore, respectfully requested that the rejection be withdrawn.

Accordingly, applicants submit that the present application is in condition for allowance.



Respectfully submitted,

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DermNet NZ

Authoritative facts about the skin from the New Zealand Dermatological Society Incorporated.

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Topical retinoids

The group of medicines known as *retinoids* are derived from Vitamin A. Creams containing the retinoids *retinol* and *retinaldehyde* can be obtained over the counter at pharmacies and supermarkets. Other topical retinoids containing *tretinoin* or *Isotretinoin* require a doctor's prescription. *Adapalene* is a related prescription medicine.

Topical retinoids can be applied to any area but are most often used on the face, the neck and the back of hands.

There are many brand name face creams that contain retinol or retinaldehyde, which are quite well tolerated and may help improve the appearance of aging skin.

The trade names of the more potent topical retinoids available on prescription in New Zealand are:

- Retin-A Cream (tretinoin)
- Isotrex Gel (isotretinoin)
- Differin Gel, Cream (adapalene)

Retinova Cream (tretinoin emollient) is no longer available. Your doctor may also import other brands of tretinoin.

Topical retinoids are effective treatments for mild to moderately severe acne. In the last few years tretinoin has also been shown to reverse some of the changes due to photo-aging, i.e. sun damage. If used long term, it may reduce some fine wrinkles, freckles, comedones (whiteheads and blackheads), and solar keratoses (dry scaly sun-spots).

Retinoids can irritate the skin and increase the chance of sunburn. Excessive use results in redness and peeling.



Dryness caused by a topical retinoid

Follow these instructions carefully:

- Use your topical retinoid on alternate nights at first. If you have very sensitive skin, wash it off after an hour or so. If it irritates, apply it less often. If it doesn't, try every night, and if possible twice daily. The skin gradually gets used to it.
- To reduce stinging, apply it to dry skin ie 30 minutes after washing.
- Apply a tiny amount to all the areas affected, and spread as far as it will go.

- Don't get it in your eyes or mouth.
- Always apply a sunscreen to exposed skin in the morning.
- Wear your usual make-up if you wish, and use cleansers and moisturisers as often as required.
- If you have acne, make sure cosmetics are oil-free.
- If your skin goes scarlet and peels dramatically even with cautious use, the retinoid may be unsuitable for your sensitive skin.

Related information

On DermNet NZ:

- Facial rejuvenation
- Fine lines and wrinkles
- Acne

DermNet does not provide an on-line consultation service.

If you have any concerns with your skin or its treatment, see a dermatologist for advice.

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Overview of other topical retinoids.

Strauss JS.

It is clear that tretinoin has a major place in the treatment of acne via its effect on the abnormal pattern of keratinization, the initial pathophysiologic event in the disease. However, for purposes of introduction, it is useful to compare tretinoin with another topical retinoid, motretinide (Ro 11-1430), which is currently used in Europe. Herein is an overview of several studies that have examined the efficacy of these two agents.

PMID: 2945845 [PubMed - Indexed for MEDLINE]

Related Links

Ro 11-1430, a new retinoic acid derivative for the topical treatment of acne. [Dermatologica. 1981]

Treatment of acne vulgaris with the retinoic acid derivative Ro 11-1430. A controlled clinical trial against retinoic acid. [Dermatologica. 1976]

The treatment of acne with topical retinoids: one approach. [Dermatologica. 1997]

Topical treatment in acne: current status and future perspectives. [Dermatologica. 2003]

The retinoic acid derivative Ro 11-1430 in Acne vulgaris. A controlled multicenter trial against retinoic acid. [Dermatologica. 1977]

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Tazarotene Is First New Generation Retinoid Treating Plaque Psoriasis

SYDNEY, Australia, June 19, 1997 -- Research presented yesterday at the World Congress of Dermatology shows tazarotene, a novel, once-daily topical retinoid aqueous indicated for the treatment of stable plaque psoriasis, an important new treatment option for patients suffering from psoriasis on up to 20 percent body surface area.

Tazarotene, the first of a new generation of topical, retinoids for the treatment of plaque psoriasis became available in Germany and Argentina under the name Zorac(R), and in the United States and Canada trade name Tazorac(TM).

While oral retinoids have long been used in the treatment of psoriasis, their use has often been limited to patients with severe psoriasis, due to the potential adverse side effects associated with their use. Patients with mild-to-moderate psoriasis to rely on topical therapies such as topical steroids, vitamin analogues, coal tar and anthralin.

"Tazarotene answers a significant need when it comes to people with psoriasis," said Madeleine Duvic, MD, Department of Dermatology, University of Texas, Medical School, Houston, Texas. "Historically, our treatment options for treating moderate to severe psoriasis have been limited, at best. Because tazarotene is highly effective and has relatively few side effects, it provides a much-needed solution for the up to three percent of the world's population suffering from this debilitating disease."

Tazarotene's Efficacy is Backed by Extensive Clinical

The key to the efficacy of tazarotene in treating plaque psoriasis lies in its ability to modulate three key pathogenic factors in psoriasis -- abnormal differentiation, hyperproliferation and inflammation. Tazarotene is thought to achieve rapid, sustained improvement in the signs and symptoms of plaque psoriasis.

efficacy by normalizing epidermal differentiation, reducing hyperproliferation and reducing the influx of inflammatory cells into the skin. In addition, its topical application directly to the skin, the site of potential psoriatic defects.

Results from large-scale clinical studies of 1,400 patients showed treatment success (defined as good, excellent or complete clearing) up to 70 percent on trunk/limb lesions and 60 percent on knee/elbow lesions with tazarotene. The onset of action was as early as one week, and therapeutic benefit was sustained in many patients up to 12 weeks after treatment.

Tazarotene Fares Well in Comparison Studies

In a comparison trial, tazarotene 0.05 percent and 0.1 percent once daily were as effective as fluocinonide (a potent topical corticosteroid) twice daily in decreasing plaque elevation and lesions, including thick knee and elbow plaques.

It also showed a significantly less likelihood of relapse after therapy was discontinued than the fluocinonide group (tazarotene 0.1%: 18 percent versus fluocinonide: 55 percent). However, as expected with a potent topical steroid, fluocinonide showed less topical irritation.

Unique Mechanism of Action

Another reason researchers believe tazarotene is so well tolerated may be because of a unique mechanism of action. When applied, tazarotene is rapidly metabolized, has a short half-life in the body and thus, has a minimal potential for accumulation in fatty tissue.

"From a theoretical standpoint, there is a good chance that, unlike other retinoids, tazarotene may selectively, rather than indiscriminately, activate selective retinoid pathways," says Roshantha Chandraratna, PhD, Director of Retinoid Research at Allergan. "The topical delivery of tazarotene, together with its suspected intrinsic pharmacological selectivity, suggests that tazarotene can be used safely on a chronic, intermittent basis to maintain a psoriasis-free state."

Tazarotene Used in Combination with Other Therapies

Tazarotene is also highly effective in reducing the severity of plaque psoriasis when used in combination with other existing therapies. For example, a multicenter, parallel-group, investigator-sponsored study found that tazarotene plus mid- or high-potency topical corticosteroids provided excellent results in reducing the overall lesional severity.

"What we found was that more than 90 percent of patients achieved treatment success (defined as a moderate, nearly almost clear or complete clearing response) when given potent corticosteroid in combination with tazarotene," Lebwohl, MD, Department of Dermatology, Mount Sinai, New York, NY, who presented the phase III data. "The data suggest that combining mid- or high-potency topical corticosteroids with tazarotene optimizes therapy."

Extensive Research Proves Tazarotene's Safety

Phase II and phase III clinical trials of more than 2,000 patients have shown that topically applied tazarotene aqueous suspension has significant efficacy with no consistent, clinically significant systemic adverse events. The most common side effects observed were mild-to-moderate local irritation, including burning and erythema.

"The extensive research we have conducted with tazarotene demonstrates that physicians can feel confident that treatment will not only improve signs and symptoms of psoriasis but also with few negative side effects," said Ronald Marks, FRCP, Department of Dermatology, University of Wales, Cardiff, who presented the research. "Although tazarotene is a relatively new therapy, we have extensive data that show it is an effective and safe treatment."

Tazarotene is contraindicated in women who are or may become pregnant. Women of childbearing potential should be aware of the potential risk and use adequate birth control measures while tazarotene is used.

Tazarotene was developed by Allergan, Inc., headquartered in Irvine, California. The company is a technology-driven health care company focused on specialty pharmaceutical products for specific disease areas that deliver value to patients, satisfy unmet needs and improve patients' lives.

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Tazarotene Is First New Generation Retinoid For Treating Plaque Psoriasis

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Rosacea Alert: Prescription Medications that may be Harmful to Rosacea Sufferers

Topics Discussed Below

- Introduction
- Topical retinoids (tretinoin)
- Caution on other topical retinoids and retinoid-like compounds
- Azelaic acid
- Benzoyl peroxide (prescription-based cleansers and creams)
- References

I. Introduction

Many anti-acne products are known to worsen rosacea symptoms. Medical experts strongly urge rosacea sufferers to stop using these products. There are several classes of topical prescription medications that rosacea sufferers should not use because the risks far out way their benefits.

II. Topical Retinoids (Tretinoin)

Topical retinoids such as retinoic acid and Vitamin A derivatives are used for the treatment of acne. Many dermatologists also use topical retinoids to treat rosacea papules and pustules. There is mounting evidence that topical retinoids such as tretinoin should not be used for treating rosacea papules or pustules because the underlying vascular disease worse. In a recent medical review, "Rosacea: Pathophysiology and Treatment" Jonathan Wilkin discusses numerous reasons why rosacea patients should not use topical retinoids such as (114)

- He states, "Tretinoin may provoke severe erythema in patients with rosacea."
- He further cautions that with tretinoin therapy, "Flushing reactions will have a more intense redness and will be an enhancement of the inflammatory process."
- Dr. Wilkin stresses, "Irritation from the tretinoin may directly exacerbate the underlying inflammation."
- He also warns, "Tretinoin may cause angiogenesis in the rosacea distribution. The tretinoin-induced angiogenesis may mask the worsening angiogenesis and telangiectasia. I have seen several patients who have facial flushing during treatment with topical tretinoin."
- He ends his discussion on tretinoin by stating, "Since rosacea appears to be in its most fundamental a vascular disorder, it would be wise to first do no harm."

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III. Caution on Other Topical Retinoids and Retinoid-Like Compounds

Due to their irritant qualities, extreme caution must be given to all topical forms of retinoic acid and vitamin derivatives. Newer formulations have been developed to lessen the potential for irritation; however, these are harsh for many rosacea sufferers. Below are a few quotes on the irritant qualities of these newer formulations.

- **Retin-A Micro™** (tretinoin gel, Ortho Pharmaceutical Corporation): Although this newer gel was developed to be less irritating, Retin-A Micro™ is still irritating to sensitive skin. *The Physicians' Desk Reference* warns, "The skin of certain individuals may become excessively dry, red, swollen, or blistered," and that, "A transient feeling of warmth or slight stinging may be noted on application." Additionally, it is warned, "Weather extremes, such as wind or cold, may be irritating to patients being treated with tretinoin".
- **Avita™** (tretinoin gel, DPT Laboratories): *The Physicians' Desk Reference* (2000) warns that, "The skin of certain individuals may become excessively red, edematous, blistered, or crusted", and that, "Applying causes a transient feeling of warmth or slight stinging". Additionally, it is warned, "Some patients at that their skin begins to take on a blush".
- **Differin™** (adapalene gel, Galderma Laboratories, Inc.): *The Physicians' Desk Reference* (2000) during treatment with this retinoid-like gel, "Some adverse effects such as erythema, scaling, dryness, pruritus, and burning will occur in 10-40% of patients". and that, "Weather extremes, such as wind may be irritating to patients under treatment with adapalene".

IV. Azelaic Acid

Azelaic acid is a dietary substance derived from whole grain cereals that can be used topically for the treatment of acne. Although a few studies demonstrate that azelaic acid is effective in the treatment of rosacea papules and pustules, there is evidence indicating that this treatment is very irritating to rosacea skin. In a recent medical investigation, researchers found that topical azelaic acid caused adverse skin reactions in 40% of the rosacea patients (patients). (137) These reactions included, "Burning, skin irritation, stinging, itching, facial edema, and scaling". Furthermore, before the actual study began, 5 patients dropped out because azelaic acid caused one or more of the following skin reactions: "Burning, erythema, skin irritation, and contact dermatitis." As discussed earlier in the report, rosacea experts stress that any topical product that causes adverse skin reactions should be avoided.

V. Benzoyl Peroxide (Prescription cleansers or creams)

Benzoyl peroxide is a popular medication that is used for acne blemishes. Rosacea experts caution that benzoyl peroxide usually worsens rosacea because it is very irritating and drying to sensitive facial skin. (130, 136) In a recent rosacea review article, "Recognizing Rosacea", Dr. Milikan from the Department of Dermatology, Tufts Medical School, indicates that benzoyl peroxide should never be used on rosacea skin. (136) In fact, Dr. Milikan indicates that benzoyl peroxide can actually induce rosacea in some patients. In cleanser or cream form, benzoyl peroxide should be avoided in most rosacea patients.

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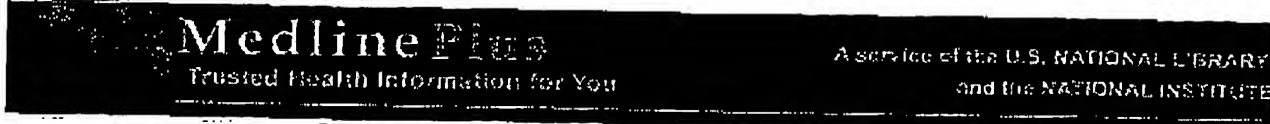
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Resorcinol (Topical)

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Resorcinol (re-SOR-si-nole) is used to treat acne, seborrheic dermatitis, eczema, psoriasis, and other skin disorders. It is also used to treat corns, calluses, and warts.

Resorcinol works by helping to remove hard, scaly, or roughened skin.

Some of these preparations are available only with your doctor's prescription. Others are available without a prescription; however, your doctor may have special instructions on the proper use of resorcinol for your medical condition.

Resorcinol is available in the following dosage forms:

Topical

- Lotion (U.S.)
- Ointment (U.S. and Canada)

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If you are using this medicine without a prescription, carefully read and follow any precautions on the label. For resorcinol, the following should be considered:

Allergies—Tell your doctor if you have ever had any unusual or allergic reaction to resorcinol. Also tell your health care professional if you are allergic to any other substances, such as preservatives or dyes.

Pregnancy—Resorcinol may be absorbed through the mother's skin. However, topical resorcinol has not been shown to cause birth defects or other problems in humans.

<http://www.nlm.nih.gov/medlineplus/druginfo/uspdi/202507.html>

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Breast-feeding—This medicine may be absorbed through the mother's skin. However, topical resorcinol has not been reported to cause problems in nursing babies.

Children—Resorcinol may be absorbed through the skin and should not be used on large areas of the bodies of infants and children. In addition, resorcinol should not be used on wounds, since doing so may cause a blood disease called methemoglobinemia.

Older adults—Many medicines have not been studied specifically in older people. Therefore, it may not be known whether they work exactly the same way they do in younger adults. Although there is no specific information comparing use of resorcinol in the elderly with use in other age groups, this medicine is not expected to cause different side effects or problems in older people than it does in younger adults.

Other medicines—Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. Tell your health care professional if you are using any other prescription or nonprescription (over-the-counter [OTC]) medicine.

Proper Use of This Medicine [Return to top](#)

It is very important that you use this medicine only as directed. Do not use more of it, do not use it more often, and do not use it for a longer time than your doctor ordered. To do so may increase the chance of absorption through the skin and the chance of resorcinol poisoning.

Apply enough resorcinol to cover the affected areas, and rub in gently.

Immediately after using this medicine, wash your hands to remove any medicine that may be on them.

Keep this medicine away from the eyes. If you should accidentally get some in your eyes, flush them thoroughly with water.

Dosing—

The dose of resorcinol will be different for different patients. *Follow your doctor's orders or the directions on the label. The following information includes only the average doses of resorcinol. If your dose is different, do not change it unless your doctor tells you to do so.*

- For *lotion* dosage form:
 - For acne, seborrheic dermatitis, eczema, or psoriasis:
 - Adults and children—Use as needed.
- For *ointment* dosage form:
 - For acne, seborrheic dermatitis, eczema, psoriasis, corns, calluses, or warts:
 - Adults and children—Use and dose must be determined by the doctor.

Missed dose—

If you miss a dose of this medicine, apply it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

Storage—

To store this medicine:

- Keep out of the reach of children.

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- Store away from heat and direct light.
- Keep the medicine from freezing.
- Do not keep outdated medicine or medicine no longer needed. Be sure that any discarded medicine is out of the reach of children.

Precautions While Using This Medicine [Return to top](#)

When using resorcinol, do not use any of the following preparations on the same affected area as this medicine, unless otherwise directed by your doctor:

- Abrasive soaps or cleansers
- Alcohol-containing preparations
- Any other topical acne preparation or preparation containing a peeling agent (for example, benzoyl peroxide, salicylic acid, sulfur, or tretinoin [vitamin A acid])
- Cosmetics or soaps that dry the skin
- Medicated cosmetics
- Other topical medicine for the skin

To use any of the above preparations on the same affected area as resorcinol may cause severe irritation of the skin.

This medicine may darken light-colored hair.

Side Effects of This Medicine [Return to top](#)

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor as soon as possible if any of the following side effects occur:

- *Less common or rare*
 - Skin irritation not present before use of this medicine
- *Symptoms of resorcinol poisoning*
 - Diarrhea, nausea, stomach pain, or vomiting; dizziness; drowsiness; headache (severe or continuing); nervousness or restlessness; slow heartbeat, shortness of breath, or troubled breathing; sweating; unusual tiredness or weakness

Other side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. However, check with your doctor if the following side effect continues or is bothersome:

- *More common*
 - Redness and peeling of skin (may occur after a few days)

Other side effects not listed above may also occur in some patients. If you notice any other effects, check with your doctor.

Brand Names [Return to top](#)

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In the U.S.—

- RA

Category [Return to top](#)

- Keratolytic, topical

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